Attorney Docket No.: ARC3254R1/ALZ5033

# **Amendments to the Claims:**

Please add new claims 32-36. This listing of claims will replace all prior versions and listings of claims in the application.

## **Listing of Claims:**

Claims 1. - 13. (Canceled)

- Claim 14. (Previously presented) A multilaminate backing construction for use with a primary drug reservoir in a drug delivery device to skin comprising:
- (a) an outer layer comprising an embossable, writable and breathable material, wherein the outer layer is embossed;
- (b) a multilaminate tie layer disposed on the skin proximal surface of the outer layer, wherein the tie layer comprises a secondary drug-containing reservoir layer; and
  - (c) a base layer disposed on the skin proximal surface of the tie layer.
- Claim 15. (Previously presented) The multilaminate backing construction of claim 14 wherein the multilaminate tie layer comprises:
  - (i) a first layer disposed on the skin proximal surface of the outer layer;
  - (ii) a second layer disposed on the skin proximal surface of the first layer;
  - (iii) a third layer disposed on the skin proximal surface of the second layer; and
  - (iv) the secondary drug-containing reservoir.

Claim 16. (Original) The multilaminate backing construction of claim 15 wherein the first layer is ethylene-vinyl acetate copolymer (EVA) or low density polyethylene (LDPE) layer; the second layer is a polyethylene terephthalate (PET) layer; the third layer is ethylene-vinyl acetate copolymer (EVA); low density polyethylene (LDPE) layer, or a polyurethane layer.

Claim 17. (Canceled)

Claim 18. (Previously presented) The multilaminate backing construction of claim 14 wherein the outer layer comprises a material selected from the group consisting of low density polyethylene (LDPE), medium density polyethylene (MDPE), high density polyethylene (HDPE), ultra high density polyethylene (UHDPE), polypropylene, and polyester.

Claim 19. (Previously presented) The multilaminate backing construction of claim 14 wherein the base layer comprises a polymeric material selected from the group consisting of polyester-polyolefin laminate, low density polyethylene (LDPE), medium density polyethylene (MDPE), high density polyethylene (HDPE), ethylene methyl acrylate copolymer (EMA), ethylene ethyl acrylate copolymer (EEA), and ethylene butyl acrylate copolymer (EBA) copolymers.

Claim 20. (Previously presented) The multilaminate backing construction of claim 14 wherein the multilaminate backing is part of a device for transdermal delivery of a drug and the secondary drug-containing reservoir has a polymeric matrix including an antagonist to the drug.

Claim 21. (Previously presented) The multilaminate backing construction of claim 14 wherein the mulilaminate backing is part of a device for transdermal delivery of a drug and the secondary drug-containing reservoir has a thermoformable polymeric matrix including an antagonist to the drug, the antagonist being dispersed in the polymeric matrix but not dissolved in the polymeric matrix.

Claim 22. (Previously presented) The multilaminate backing construction of claim 14 wherein the mulilaminate backing is part of a device for transdermal delivery of a drug and wherein the secondary drug-containing reservoir has a polymeric matrix and dispersed in the polymeric matrix is a particulate antagonist to the drug.

Claim 23. (Previously presented) The multilaminate backing construction of claim 14 wherein the mulilaminate backing is part of a device for transdermal delivery of a drug to the skin, the secondary drug-containing reservoir includes an antagonist to the drug and wherein the outer layer controls the release of the antagonist.

#### Claim 24. (Canceled)

Claim 25. (Previously presented) The multilaminate backing construction of claim 14 wherein the outer layer is made of a material selected from the group consisting of microporous, microfibrullar materials and combinations thereof.

Claim 26. (Previously presented) The multilaminate backing construction of claim 14 wherein the outer layer is part of a device for transdermal delivery of a drug to the skin, and the secondary drug-containing reservoir contains an antagonist to the drug, the antagonist being selected from a group consisting of naltrexone, methylnaltrexone, naloxone, nalbuphine, nalorphine, nalorphine dinicotinate, nalmefene, nadide, levallorphan, cyclozocine and pharmaceutically acceptable salts thereof.

Claim 27. (Previously presented) The multilaminate backing construction of claim 14 wherein the multilaminate backing is part of a device for transdermal delivery of a drug to the skin, the secondary drug-containing reservoir includes an antagonist to the drug and wherein the outer layer is microporous and controls the release of the antagonist and the base layer is not permeable to the antagonist such that the antagonist is not delivered to the skin.

Claim 28. (Previously presented) The multilaminate backing construction of claim 14 wherein the multilaminate tie layer comprises:

- (i) a first layer disposed on the skin proximal surface of the outer layer;
- (ii) a second layer disposed on the skin proximal surface of the first layer;
- (iii) a third layer disposed on the skin proximal surface of the second layer; and

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(iv) a secondary drug-containing reservoir containing particles of an antagonist to a drug, the particles dispersed in a polymeric matrix in the drug-containing reservoir; wherein the multilaminate backing construction is part of a device for delivery of the drug and outer layer controls release of the antagonist for deterrence against drug abuse and wherein the embossable outer layer is microporous and not laminated on a layer that is one of a pressure sensitive adhesive and a high density polyethylene such that the embossable outer layer is not permanently clear.

Claim 29. (Previously presented) The multilaminate backing construction of claim 14 wherein the secondary drug-containing reservoir has a polymeric matrix and includes an antagonist that is not permeable through the base layer and wherein the outer layer is an antagonist release rate controlling layer.

Claim 30. (Previously presented) The multilaminate backing construction of claim 14 wherein the tie layer does not contain pressure sensitive adhesive or high density polyethylene next to the outer layer.

- Claim 31. (Currently amended) A multilaminate backing construction for use with a primary drug reservoir in a drug delivery device to skin comprising:
- (a) an outer layer comprising an embossable, writable and breathable microporous material, the outer layer being rate-controlling to an antagonist of a drug, wherein the outer layer is embossed;
- (b) a multilaminate tie layer, the tie layer disposed on the skin proximal surface of the outer layer and including a first layer disposed on the skin proximal surface of the outer layer and at least one additional layer disposed on the skin proximal surface of the first layer, a secondary drug-containing reservoir layer being one of the at least one additional layer, the secondary drug-containing reservoir <u>layer</u> including a polymeric matrix with antagonist-containing particles dispersed therein, the antagonist being selected from a group consisting of naltrexone, methylnaltrexone, naloxone, nalbuphine, nalorphine, nalorphine dinicotinate, nalmefene, nadide, levallorphan, cyclozocine and pharmaceutically acceptable salts thereof; and

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(c) a base layer disposed on the skin proximal surface of the tie layer, the base layer being impermeable to the antagonist preventing permeation thereof to the skin.

Claim 32. (New) The multilaminate backing construction of claim 14 wherein the multilamiante tie layer has at least two layers of different materials.

Claim 33. (New) The multilaminate backing construction of claim 14 wherein the backing construction is a backing in a transdermal drug delivery system having a primary drug reservoir having a primary drug; and wherein the secondary drug-containing reservoir layer contains a secondary drug different from the primary drug.

Claim 34. (New) The multilaminate backing construction of claim 14 wherein the backing construction is a backing in a transdermal drug delivery system having a primary drug reservoir having a primary drug; and wherein the secondary drug-containing reservoir layer contains an antagonist of the primary drug.

## Claim 35. (New) A transdermal drug delivery patch, comprising:

- (a) multilaminate backing construction including:
  - (i) an outer layer comprising an embossed, writable and breathable material;
  - (ii) a multilaminate tie layer disposed on the skin proximal surface of the outer layer, wherein the tie layer comprises a secondary drug-containing reservoir layer having a second drug different from a first drug;
  - (iii) a base layer disposed on the skin proximal surface of the tie layer;
- (b) peelable protective layer; and
- (c) primary drug reservoir disposed between the multilaminate backing construction and the peelable protective layer, the primary drug reservoir having the first drug.

## Claim 36. (New) A transdermal drug delivery patch, comprising:

- (a) multilaminate backing construction including:
  - (i) an outer layer comprising an embossed, writable and breathable material;

- (ii) a multilaminate tie layer disposed on the skin proximal surface of the outer layer, wherein the tie layer comprises a secondary drug-containing reservoir layer having a second drug different from a first drug;
- (iii) a base layer disposed on the skin proximal surface of the tie layer;
- (b) peelable protective layer; and
- (c) primary drug reservoir disposed between the multilaminate backing construction and the peelable protective layer, the primary drug reservoir having the first drug; wherein the second drug is an antagonist of the first drug.